Reply to Office Action of June 3, 2009

REMARKS/ARGUMENTS

Claims 19, 21-26, and 28-34 are pending and were examined. Reexamination and reconsideration of the claims, in view of the following remarks, are respectfully requested.

Independent claim 19 and claims 21-26 and 28 dependent thereon were rejected as being obvious over the combination of Keegan '474 and McGuckin '976. Such rejections are respectfully traversed.

Applicants respectfully submit that the Examiner has misunderstood the teachings of Keegan. Keegan, in relevant part as relied on by the Examiner, teaches a catheter for delivering a separate embolic filter element onto a guidewire. The delivery catheter may then be removed with the guidewire and embolic filter left in place and a separate interventional catheter used to treat the blood vessel. After treating, a separate retrieval catheter can be used to retrieve the embolic filter. The embolic filter is well illustrated in Fig. 1 and the procedure well illustrated in Figs. 2 through 13.

Applicants believe that the Examiner has mischaracterized Keegan in at least the following respects:

1. The Examiner asserts that Fig. 5 of Keegan shows an expansible member 26 "disposed on the distal end of the tubular member, the first expansible member having a contracted configuration and an expanded configuration, wherein the first expansible member consists essentially of a single wire (26) that can be retracted into the lumen of the tubular member (capable of being retracted into lumen) to shift the single wire from a helical expanded configuration to a straightened contracted configuration." Such characterization is simply inaccurate.

The element 26 shown in Fig. 5 is a "snaring hook," which may have a J-shaped or C-shaped structure (based on its appearance), but certainly is not shown or described as having a helical structure. The Examiner is directed to Fig. 13 to show what the hook 26 looks like as it is being retracted back into a separate retrieval catheter.

Applicants further note that the hook number 26 is not disposed on the distal end of the tubular member. It is completely separate from tubular member 21 and the hook 26 and

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filter 20 are delivered from the helical end, as shown in Figs. 4 and 5, clearly showing that there is no connection.

- 2. The Examiner further asserts that Keegan shows "a first deformable membrane . . . [is] . . . at least partially disposed over the first expansible member in the expanded configuration (20) Fig. 5." Such is not the case. The attachment of the hook 26 to the filter 20 is not ever shown. Indeed, nowhere does the '474 publication ever suggest that the filter needs support since it will be opened by blood flow passing through the filter and may not require internal support, other than perhaps a hoop at the entrance.
- 3. The Examiner further characterizes the separate stent delivery balloon as being "a second expansible member (balloon, Fig. 6) disposed proximal to the first expansible member and on the distal end of the tubular member." As discussed above, such is not the case since the "tubular member 21" relied on by the Examiner is in fact a separate catheter than the balloon catheter which is introduced over guidewire 10 in Fig. 6. It is further noted that the angioplasty balloon is intended to be in a blood vessel, and not to extend into any tissue tract between the blood vessel and the skin surface.
- 4. Nor does Keegan '474 teach that "a predetermined volume of air contained within the tubular member inflates the second expansible member" Again, the tubular member 21 is not in any way connected to the balloon shown in Fig. 6. The catheter of Fig. 6, in contrast, is in no way connected to the filter 20 so cannot be the tubular member claimed herein.

For all these reasons, Keegan fails to teach the elements of claim 19 as asserted by the Examiner.

Nor does McGuckin cure the deficiencies of Keegan. The Examiner relies on McGuckin to teach a "first deformable membrane having a spherical shape . . . and [a] second second expansible member comprising a coil or spring of wire with a membrane." Even if that is the case, that would not cure the clear deficiencies of Keegan described above. For these reasons, Applicants believe that independent claim 19, without amendment, distinguishes Keegan and McGuckin as Keegan fails to set forth the essential elements of the claim as noted above.

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Independent method claim 29 has been rejected over Keegan and McGuckin, further in view of Brenneman '300. The Examiner relies on Keegan and McGucken as teaching "the claimed invention as described in the above rejection" except for the "specified locations of the first and second expansible members." The Examiner relies on Brenneman as teaching "the first expansible member as deployed against a blood vessel wall (Fig. 1) and the second expansible member as deployed against a tissue tract (Fig. 2). Applicants respectfully traverse such rejections.

For all the reasons stated above, Keegan fails to teach placing its device anywhere in the tissue tract. Both Keegan and McGuckin are directed at devices intended for embolic protection. Such devices are deployed in the blood vessel and would not have any balloons, membranes, springs, or any other expandable components placed in the tissue tract. Brenneman, in contrast, is intended for the sealing of a blood vessel puncture but fails to have the specific structures set forth in claim 19 herein. Those specific structures, however, are absent from Keegan and McGuckin for the reasons discussed above with respect to claim 1.

In particular, independent method claim 29 specifically recites the step of "causing a straight wire within the first expansible member to assume a helical configuration such that the wire expands the first expansible member to an expanded configuration comprising a spherical shape" within the lumen of the blood vessel. Neither Keegan, McGuckin, nor Brenneman ever teach such a step. A "single wire 26" relied on by the Examiner is in fact a retrieval hook that is never illustrated as being straight and is certainly never shown to assume a helical configuration within the filter 26 in order to expand it into a spherical or any other shape.

Nor does Keegan, McGuckin, or Brenneman ever teach deploying a second expansible member having an elongate cylindrical shape. The second balloon of McGuckin is never shown or suggested to have an elongate cylindrical shape. Nor is the second balloon of Brenneman, and Keegan nowhere has a second expansible element.

For these reasons, the Office Action fails to set forth even a *prima facie* showing of the obviousness of independent claim 19. Thus, independent claim 19, as well as all claims dependent thereon, are believed to be in condition for allowance.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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Attachments
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